Figure 4 shows the result of printing one of the 3D views as obtained after applying the AVS program.

Figure 5 shows an example of comparing a macroscopic histological section of eyeball No. 3 (left-hand picture) with an ultrasound microscopic section (right-hand picture) passing through the same macular region.- -

Please add Figure 6 to the drawings.

--Figure 6 is a block diagram showing the main parts of the system.--

Abstract

Please delete the title of the invention, which appears as the first paragraph of the Abstract, spanning lines 3-6, page 25.

REMARKS

Prior to entry of the claim amendments presented above, claims 1-31 were pending in the application. Claims 1-31 were rejected. Accordingly, claims 1-31 are pending.

Drawings

In response to the Examiner's request for a drawing of the invention, applicant attaches hereto Figure 6, a block diagram showing main features of the invention.

Rejections Under 35 USC §112, Second Paragraph

Claims 5-11 and 28-31 stand rejected under 35 USC § 112, second paragraph, for indefiniteness. Applicant submits that this rejection is improper because one of ordinary skill in the art would understand the configuration of the claimed device in light of the specification.

Rejections Under 35 USC §102

Claims 1, 2, 5, 10, 12, 13, 17-19, and 27-31 stand rejected under 35 USC § 102(b) as being anticipated by Silverman et al. Applicant traverses this rejection. The Examiner considers that Silverman et al. ("Three-dimensional High frequency Ultrasonic Parameter

Imaging of Anterior Segment pathology," Ophthalmology 1995) teaches at page 838, column 2, a method and device for ultrasound deep penetration and tissue characterization of human eye by step and structure for providing an ultrasound transducer having a nominal excitation frequency of 50 Mhz and a focal length of 12 mm.

This article is concerned with an ultrasonic imaging of the **anterior** segment pathology of the eye. The ultrasound system described in this publication uses a polymer transducer with a nominal frequency of 50 Mhz and a 12-mm focal length. Further on, the article explains how the ultrasound system is used. The patient being in a supine position, the steridrape supported by a ringstand, and approximately one-half liter 37°C normal saline is poured into the reservoir formed by the steri-drape. The transducer then is lowered into the saline and its range to the eye is adjusted to place the area of interest in the focal plane. This generally allows a separation of approximately 1cm between the transducer and the eye.

This is clear evidence that this device only allows an ultrasound penetration of about a maximum of 4-5 mm. As a consequence, such a device is only able to analyze the cornea, but certainly not the posterior part of the eyeball and more particularly the macular region. This can be confirmed by U.S. Patent No. 5,369,454, listed as Reference A on the Form 892 of outstanding Office Action. The disclosure of this patent corresponds, with Ronald H. Silverman listed as one of the inventors, to the device described in the Silverman article. The position of the transducer (20) relatively to the eye is shown in figure 1.

Therefore, the article by Silverman neither describes nor suggests the possibility of exploring the posterior segment of the eyeball with precision.

Claims 1, 2, 5, 10, 11, 13, and 19 are rejected under 35 USC § 102(b) as being anticipated by Lockwood et al. (US 5,412,854). Applicant also traverses this rejection. U.S. Patent No. 5,412,854 (Lockwood et al.) is only concerned with describing a method of making a high frequency focused transducer by using a piezoelectric or ferroelectric wafer. The Examiner considers that this patent teaches the use of such a transducer in an ultrasound imaging system for visualization of the interior structure of a human eye. This reference mentions only in the Description of the Related Art, that recently, a number of new ultrasound imaging systems have been developed for visualization of the eye, skin **endoluminal structures and intravascular structures** at frequencies greater than 20 Mhz

with no precision on focal length and no reference on ultrasound penetration. Furthermore, it is clear that such a system presented in a very general way, only corresponds to invasive exploring methods which require surgical operations. Contrary to these techniques, the present invention is concerned with echographic non-invasive explorations.

Claims 1, 2, 5, 10, 12, 13, 17-19, and 27-31 stand further rejected under 35 USC § 102(e) as being anticipated by Silverman et al. (US 5,776,068). Applicant contends that this rejection is also without merit. As stated before in connection with the other Silverman publication, it appears that such a device is only able to achieve a very short penetration since, even if the transducer is focused at about 10 mm, it is coupled to the eye via a saline solution.

Furthermore, the transducer is positioned along the optical axis of the eye and is only able to give biometric determination of the anterior segment anatomy of the eye (the cornea, iris, etc.), as confirmed column 3, lines 57-65.

Contrary to such homogeneous teachings from Silverman's publications, the present invention uses an ultrasound transducer having a long focal length, greater than 10 mm, preferably about 25 mm, in order to be able to realize echographic explorations of human or animal tissues and more particularly, the posterior segment of the eyeball.

None of the cited documents mentions the possibility of using a transducer with such a long focal length.

The effect obtained with that kind of focusing, i.e. the possibility of exploring with precision at great depth so as to be able to explore the posterior segment of the eyeball, must be considered as being unexpected since the prior art would appear to discourage the person skilled in the art from exploring the use of high frequency ultrasound (50 Mhz to 80 Mhz), i.e. at high resolution, when seeking to explore the posterior segment of the eyeball.

Applicant also notes paragraph 3 of the International Preliminary Examination Report, which emphasizes the fact that the authors of:

> - D1: "Three-dimensional highfrequency ultrasonic parameter imaging of anterior segment pathology," OPHTHALMOLOGY, Vol. 102, no. 5, May 1995, pp. 837-843 (Reference A3 of the acknowledged 1449), and

- D2: "Substrate ultrasound microscopic imaging of the intact eye," OPHTHALMOLOGY, Vol. 97, no. 2, February 1990, pp. 244-250 (Reference A4 of the acknowledged 1449)

state explicitly that it is impossible to explore the posterior segment of the eye with a transducer having a high excitation frequency, i.e. lying in the range of 50 to 100 Mhz (D1 (A3), page 837, right-hand column and page 838, left-hand column, first paragraph and D2 (A4), page 250).

Rejections Under 35 USC §103(a)

Claims 14-16 and 20-22 are rejected under USC §103(a) as being unpatentable over Zeimer (US 4,883,061). Applicant respectfully traverses the rejection. Applicant would like to draw the Examiner's attention to the fact that U.S. Patent No. 4,883,061 (Zeimer) is in fact related with a method and apparatus for measuring the thickness of eye components, using a beam of light for analyzing anterior and posterior surfaces of the retina. However, such a technique using a beam of light cannot be considered as an echographic exploration device and would certainly not have provided motivation to reach the subject matter of the present invention.

A device using a beam of light is not able to penetrate through the pars plana. That means that such a system can only be used for investigating the posterior part of the retina of the eye through the pupil. Therefore, the posterior segment of the eyeball can only be investigated in a very limited manner, i.e. only on the macular region placed in the axis of the pupil.

Moreover, such a device based on the use of a beam of light cannot be used in specific cases such as when the transparency of the vitrous humor of the eye is affected for example, by internal bleeding, or in case of cataract.

Claims 3, 4, 6-9 and 23 are rejected under USC §103(a) as being unpatentable over Silverman et al in view of Coleman et al (US 5,331,962) or Reinstein et al. (US 5,293,871). Applicant traverses this rejection. These references only confirm that ultrasonic biometer images had only been obtained on the one corneal layer, that means at the anterior part of the eyeball. Therefore, the combination of these references does not render the claimed invention obvious.

CONCLUSION

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

April 18, 2002
Date

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

AMENDED VERSION TO SHOW CHANGES MADE IN THE ABSTRACT

A B S T R A C T

[~~THE USE OF AN ULTRASOUND TRANSDUCER FOR ECHOGRAPHIC EXPLORATION OF TISSUES OR ORGANS OF THE HUMAN OR ANIMAL BODY, IN PARTICULAR OF THE POSTERIOR SEGMENT OF THE EYEBALL~~]

The present invention relates to the use of a high frequency ultrasound transducer with long focal length for making a device and for implementing a method of echographic exploration of tissue or organs of the human or animal body. More particularly, the invention relates to using an ultrasound transducer having a nominal excitation frequency greater than 20 MHz, preferably lying in the range 50 MHz to 80 MHz, with long focal length, greater than 10 mm, preferably about 25 mm, for making a device for echographic exploration of the eyeball, in particular of the posterior segment of the eyeball, and more particularly of the macular region.

Translation of the title and the abstract as published by the PCT Authorities, possibly after making changes, ex officio, e.g. under PCT Rules 37.2, 38.2, and/or 48.3.